



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Gillies et al.  
SERIAL NO.: 10/256,156 GROUP NO.: 1647  
FILING DATE: February 24, 1999 EXAMINER: Hunnicutt, Rachel Kapust  
TITLE: Enhancing the Circulating Half Life of Antibody Based Fusion Proteins

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the non-U.S. patent documents and non-patent publications are enclosed.

**REMARKS**

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

(1) within three (3) months of the **filings date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or

(2) after the period defined in (1) above but before the mailing date of any of a **final action** under 37 C.F.R. 1.113, a **notice of allowance** under 37 C.F.R. 1.311, or an action that otherwise closes prosecution in the application, and

the requisite Statement is below, OR

the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein; or

Supplemental Information Disclosure Statement

Serial No. 09/256,156

Page 2 of 2

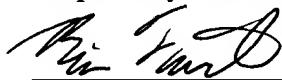
(3) after the period defined in (2) above but before the payment of the issue fee, AND

the requisite Statement is below, AND

the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Respectfully submitted,



---

Brian A. Fairchild  
Attorney for the Applicants  
Kirkpatrick & Lockhart Nicholson  
Graham LLP  
75 State Street  
Boston, Massachusetts 02109-1808

Date: March 30, 2005  
Reg. No. 48,645

Tel. No.: (617) 261-3169  
Fax No.: (617) 261-3175

BOS-823554 v1



FORM PTO - 1449

SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT

ATTORNEY DOCKET NO.: LEX-003

APPLICANT(S): Gillies *et al.*

SERIAL NO.: 09/256,156

FILING DATE: February 24, 1999 GROUP: 1647

## U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A111	4,522,811	6/1/85	Eppstein <i>et al.</i>			
	A112	4,667,016	5/19/87	Lai <i>et al.</i>			
	A113	4,732,683	3/22/88	Georgiades <i>et al.</i>			
	A114	4,737,462	4/12/88	Mark <i>et al.</i>			
	A115	4,975,369	12/4/90	Beavers <i>et al.</i>			
	A116	5,082,658	1/21/92	Palladino			
	A117	5,091,513	2/25/92	Huston <i>et al.</i>			
	A118	5,399,346	3/21/95	Anderson <i>et al.</i>			
	A119	5,428,130	6/27/95	Capon <i>et al.</i>			
	A120	5,480,981	1/2/96	Goodwin <i>et al.</i>			
	A121	5,589,466	12/31/96	Felgner <i>et al.</i>			
	A122	5,614,184	3/25/97	Sytkowski <i>et al.</i>			
	A123	5,712,120	1/27/98	Rodriguez <i>et al.</i>			
	A124	5,738,852	4/14/98	Robinson <i>et al.</i>			
	A125	5,795,779	8/18/98	McCormick			
	A126	5,827,703	10/27/98	Debs <i>et al.</i>			
	A127	5,837,821	11/17/98	Wu <i>et al.</i>			
	A128	5,888,773	3/30/99	Jost <i>et al.</i>			
	A129	6,281,010	8/28/01	Gao <i>et al.</i>			
	A130	6,291,158	9/18/01	Winter <i>et al.</i>			
	A131	6,627,615	9/30/03	Debs <i>et al.</i>			
	A132	2004/0180035	9/16/04	Gillies <i>et al.</i>			

EXAMINER	DATE CONSIDERED

FORM PTO - 1449  SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT					ATTORNEY DOCKET NO.: LEX-003  APPLICANT(S): Gillies <i>et al.</i>  SERIAL NO.: 09/256,156  FILING DATE: February 24, 1999 GROUP: 1647				
---	--	--	--	--	---	--	--	--	--

## FOREIGN PATENT DOCUMENTS

EXAM INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B108	0 428 267 B1	12/11/96	EP					Y
	B109	0 428 596 B1	4/17/96	EP					Y
	B110	0 433 827 B1	3/4/98	EP					Y
	B111	0 519 596 A1	12/23/92	EP					Y
	B112	0 668 351 B1	9/22/99	EP					Y
	B113	0 699 755 A2	3/6/96	EP					Y
	B114	2 188 638	10/7/87	GB					Y
	B115	WO 92/10755	6/25/92	PCT					Y
	B116	WO 94/25609	11/10/94	PCT					Y
	B117	WO 96/40792	12/19/96	PCT					Y
	B118	WO 98/52976	11/26/98	PCT					Y
	B119	WO 00/01822	1/13/00	PCT					Y
	B120	WO 02/074783	9/26/02	PCT					Y

EXAMINER	DATE CONSIDERED
----------	-----------------

<b>FORM PTO - 1449</b> <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>		<b>ATTORNEY DOCKET NO.: LEX-003</b> <b>APPLICANT(S): Gillies <i>et al.</i></b> <b>SERIAL NO.: 09/256,156</b> <b>FILING DATE: February 24, 1999</b> <b>GROUP: 1647</b>
<b>OTHER ART, JOURNAL ARTICLES, ETC.</b>		
<b>EXAM. INIT.</b>	<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>	
C260	Aichele <i>et al.</i> , (1994), "Peptide-Induced T-Cell Tolerance to Prevent Autoimmune Diabetes in a Transgenic Mouse Model," <u>Proc. Natl. Acad. Sci. USA</u> , 91:444-448.	
C261	Altschul <i>et al.</i> , (1990), "Basic Local Alignment Search Tool," <u>J. Mol. Biol.</u> , 215:403-10.	
C262	Altschul <i>et al.</i> , (1997), "Gapped BLAST and PSI-BLAST: A New Generation of Protein Database Search Programs," <u>Nucleic Acids Res.</u> , 25(17):3389-3402.	
C263	Anderson <i>et al.</i> , (1980), "Characterization of the Fc Receptor for IgG on a Human Macrophage Cell Line U937," <u>J. Immunol.</u> , 125(6):2735-41.	
C264	Anderson <i>et al.</i> , (1994), "Effects of Route and Formulation on Clinical Pharmacokinetics of Interleukin-2," <u>Clin. Pharmacokinet.</u> , 27(1):19-31.	
C265	Baici <i>et al.</i> , (1980), "Kinetics of the Different Susceptibilities of the Four Human Immunoglobulin G Subclasses to Proteolysis by Human Lysosomal Elastase," <u>Scand. J. Immunol.</u> , 12(1):41-50.	
C266	Barbulescu <i>et al.</i> , (1998), "IL-12 and IL-18 Differentially Regulate the Transcriptional Activity of the Human IFN- $\gamma$ Promoter in Primary CD4+ T Lymphocytes," <u>J. Immunol.</u> , 160:3642-7.	
C267	Bednarek <i>et al.</i> , (1991), "Soluble HLA-A2.1 Restricted Peptides that are Recognized by Influenza Virus Specific Cytotoxic T Lymphocytes," <u>J. Immunol. Methods</u> , 139:41-47.	
C268	Benacerraf <i>et al.</i> , (1959), "The Clearance of Antigen Antibody Complexes from the Blood by the Reticulo-Endothelial System," <u>J. Immunol.</u> , 82:131-7.	
C269	Böhm, (1994), "On the Use of LUDI to Search the Fine Chemicals Directory for Ligands of Proteins of Known Three-Dimensional Structure," <u>J. Comput. Aided Mol. Des.</u> , 8:623-32.	
C270	Böhm, (1994), "The Development of a Simple Empirical Scoring Function to Estimate the Binding Constant for a Protein-Ligand Complex of Known Three-Dimensional Structure," <u>J. Comput. Aided Mol. Des.</u> , 8(3):243-56.	
C271	Böhm, (1998), "Prediction of Binding Constants of Protein Ligands: A Fast Method for the Prioritization of Hits Obtained from De Novo Design or 3D Database Search Programs," <u>J. Comput. Aided Mol. Des.</u> , 12(4):309-23.	
C272	Boshart <i>et al.</i> , (1985), "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," <u>Cell</u> , 41:521-530.	
C273	Boulianne <i>et al.</i> , (1984), "Production of Functional Chimaeric Mouse/Human Antibody," <u>Nature</u> , 312:643-6.	
C274	Bourgois <i>et al.</i> , (1974), "Determination of the Primary Structure of a Mouse IgG2a Immunoglobulin: Amino-Acid Sequence of the Fc Fragment: Implications for the Evolution of Immunoglobulin Structure and Function," <u>Eur. J. Biochem.</u> , 43:423-35.	
C275	Brambell <i>et al.</i> , (1964), "A Theoretical Model of $\gamma$ -Globulin Catabolism," <u>Nature</u> , 203:1352-55.	
C276	Brazolot Millan <i>et al.</i> , (1998), "CpG DNA Can Induce Strong TH1 Humoral and Cell-Mediated Immune Responses against Hepatitis B Surface Antigen in Young Mice," <u>Proc. Natl. Acad. Sci. USA</u> , 95:15553-8.	

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
-----------------	------------------------

FORM PTO - 1449  SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO.: LEX-003  APPLICANT(S): Gillies <i>et al.</i>  SERIAL NO.: 09/256,156  FILING DATE: February 24, 1999 GROUP: 1647
--	---

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
C277	Brekke <i>et al.</i> , (1994), "Human IgG Isotype-Specific Amino Acid Residues Affecting Complement-Mediated Cell Lysis and Phagocytosis," <u>Eur. J. Immunol.</u> , 24:2542-2547.
C278	Brem <i>et al.</i> , (1993), "The Combination of Antiangiogenic Agents to Inhibit Primary Tumor Growth and Metastasis," <u>J. Pediatr. Surg.</u> , 28(10):1253-7.
C279	Brooks <i>et al.</i> , (1983), "CHARMM: A Program for Macromolecular Energy, Minimization, and Dynamics Calculations," <u>J. Comput. Chemistry</u> , 4:187-217.
C280	Broudy <i>et al.</i> , (1988), "Recombinant Human Erythropoietin: Purification and Analysis of Carbohydrate Linkage," <u>Arch. Biochem. Biophys.</u> , 265:329-36.
C281	Bubenik <i>et al.</i> , (1995), "Interleukin-2 Gene Therapy of Residual EL-4 Leukaemia Potentiates the Effect of Cyclophosphamide Pretreatment," <u>J. Cancer Res. Clin. Oncol.</u> , 121:39-43.
C282	Bumol <i>et al.</i> , (1982), "Unique Glycoprotein-Proteoglycan Complex Defined by Monoclonal Antibody on Human Melanoma Cells," <u>Proc. Natl. Acad. Sci. USA</u> , 79:1245-9.
C283	Carnemolla <i>et al.</i> , (1989), "A Tumor-Associated Fibronectin Isoform Generated by Alternative Splicing of Messenger RNA Precursors," <u>J. Cell. Biol.</u> , 108:1139-1148.
C284	Carnemolla <i>et al.</i> , (1992), "The Inclusion of the Type III Repeat ED-B in the Fibronectin Molecule Generates Conformational Modifications that Unmask a Cryptic Sequence," <u>J. Biol. Chem.</u> , 267(34):24689-24692.
C285	Cazzola <i>et al.</i> , (1998), "Red Blood Cell Precursor Mass as an Independent Determinant of Serum Erythropoietin Level," <u>Blood</u> , 91:2139-45.
C286	Chan <i>et al.</i> , (1992), "Mechanisms of IFN- $\gamma$ Induction by Natural Killer Cell Stimulatory Factor (NKSF/IL-12). Role of Transcription and mRNA Stability in the Synergistic Interaction Between NKSF and IL-2," <u>J. Immunol.</u> , 148:92-98.
C287	Chappel <i>et al.</i> , (1991), "Identification of the Fc Gamma Receptor Class I Binding Site In Human IgG Through Use of Recombinant IgG1/IgG2 Hybrid and Point-Mutated Antibodies," <u>Proc. Natl. Acad. Sci. USA</u> , 88(20):9036-40.
C288	Cheetham, (1998), "NMR Structure of Human Erythropoietin and a Comparison with its Receptor Bound Conformation," <u>Nat. Struct. Biol.</u> , 5:861-6.
C289	Ciardiello <i>et al.</i> , (1996), "Antitumor Activity of Combined Blockade of Epidermal Growth Factor Receptor and Protein Kinase A," <u>J. Natl. Cancer Inst.</u> , 88:1770-6.
C290	Cirulli <i>et al.</i> , (1998), "KSA Antigen Ep-CAM Mediates Cell-Cell Adhesion of Pancreatic Epithelial Cells: Morphoregulatory Roles in Pancreatic Islet Development," <u>J. Cell Biol.</u> , 140:1519-34.
C291	Cohen <i>et al.</i> , (1998), "An Artificial Cell-Cycle Inhibitor Isolated from a Combinatorial Library," <u>Proc. Natl. Acad. Sci. USA</u> , 95:14272-7.
C292	Congote <i>et al.</i> , (1984), The Erythrotropins, New Erythroid Cell Stimulate Factors Extracted From Human and Bovine Fetal Tissues," Abstract 364, "Proceedings 7 <sup>th</sup> Intl. Congress of Endocrinology," Quebec City, Quebec, July 1-7, 1984.

EXAMINER	DATE CONSIDERED
----------	-----------------

FORM PTO - 1449  SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO.: LEX-003  APPLICANT(S): Gillies <i>et al.</i>  SERIAL NO.: 09/256,156  FILING DATE: February 24, 1999 GROUP: 1647
--	---

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
C293	Congote, (1983), "Isolation of Two Biologically Active Peptides, Erythrotropin I and Erythrotropin II from Fetal Calf Intestine," <u>Biochem. Biophys. Res. Commun.</u> , 115(2):477-83.
C294	Congote, (1984), "Extraction from Fetal Bovine Serum of Erythrotropin, an Erythroid Cell-Stimulating Factor," <u>Anal. Biochem.</u> , 140:428-33.
C295	Cosenza <i>et al.</i> , (1997), "Disulfide Bond Assignment in Human Interleukin-7 by Matrix-Assisted Laser Desorption/Ionization Mass Spectroscopy and Site-Directed Cysteine to Serine Mutational Analysis," <u>J. Biol. Chem.</u> , 272:32995-3000.
C296	Cunningham <i>et al.</i> , (1989), "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis," <u>Science</u> , 244:1081-85.
C297	Curiel <i>et al.</i> , (1991), "Adenovirus Enhancement of Transferrin-Polylysine-Mediated Gene Delivery," <u>Proc. Natl. Acad. Sci. USA</u> , 88:8850-4.
C298	Dauber-Osguthorpe <i>et al.</i> , (1988), "Structure and Energetics of Ligand Binding to Proteins: Escherichia Coli Dihydrofolate Reductase-Trimethoprim, A Drug-Receptor System," <u>Proteins</u> , 4:31-47.
C299	Daugherty <i>et al.</i> , (1991), "Polymerase Chain Reaction Facilities the Cloning, CDR-Grafting, and Rapid Expression of a Murine Monoclonal Antibody Directed Against the CD18 Component of Leukocyte Integrins," <u>Nucleic Acid Res.</u> , 19:2471-2476.
C300	De Bruijn <i>et al.</i> , (1995), "Phagocyte-Induced Antigen-Specific Activation of Unprimed CD8+ T Cells in Vitro," <u>Eur. J. Immunol.</u> , 25:1274-85.
C301	Delorme <i>et al.</i> , (1992), "Role of Glycosylation on the Secretion and Biological Activity of Erythropoietin," <u>Biochemistry</u> , 31:9871-6.
C302	Desai <i>et al.</i> , (1992), "IL-12 Receptor. II. Distribution and Regulation of Receptor Expression," <u>J. Immunol.</u> , 148:3125-32.
C303	Donnelly <i>et al.</i> , (1993), "Targeted Delivery of Peptide Epitopes to Class I Major Histocompatibility Molecules by a Modified Pseudomonas Exotoxin," <u>Proc. Natl. Acad. Sci. USA</u> , 90:3530-4.
C304	Donnelly <i>et al.</i> , (1997), "DNA Vaccines," <u>Annu. Rev. Immunol.</u> , 15:617-48.
C305	Dube <i>et al.</i> , (1988), "Glycosylation at Specific Sites of Erythropoietin is Essential for Biosynthesis, Secretion, and Biological Function," <u>J. Biol. Chem.</u> , 263:17516-21.
C306	Ellison <i>et al.</i> , (1982), "The Nucleotide Sequence of a Human Immunoglobulin C $\gamma_1$ Gene," <u>Nucleic Acids Res.</u> , 10:4071-9.
C307	Faas <i>et al.</i> , (1993), "Phenotypically Diverse Mouse Thymic Stromal Cell Lines which Induce Proliferation and Differentiation Of Hematopoietic Cells," <u>Eur. J. Immunol.</u> , 23:1201-14.
C308	Farner <i>et al.</i> , (1995), "Distinction Between $\gamma_c$ C Detection and Function in YT Lymphoid Cells and in the Granulocyte-Macrophage Colony-Stimulating Factor-Responsive Human Myeloid Cell Line, Tf-1," <u>Blood</u> , 86:4568-78.
C309	Fawell <i>et al.</i> , (1994), "Tat-Mediated Delivery of Heterologous Proteins into Cells," <u>Proc. Natl. Acad. Sci. USA</u> , 91:664-8.

EXAMINER	DATE CONSIDERED
----------	-----------------

FORM PTO - 1449  SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO.: LEX-003  APPLICANT(S): Gillies <i>et al.</i>  SERIAL NO.: 09/256,156  FILING DATE: February 24, 1999 GROUP: 1647
--	---

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
C310	Fu <i>et al.</i> , (1993), "The Sheep Erythropoietin Gene: Molecular Cloning and Effect of Hemorrhage on Plasma Erythropoietin and Renal/Liver Messenger RNA in Adult Sheep," <u>Mol. Cell. Endocrinol.</u> , 93:107-16.
C311	Gainsford <i>et al.</i> , (1996), "Leptin Can Induce Proliferation, Differentiation, and Functional Activation of Hemopoietic Cells," <u>Proc. Natl. Acad. Sci. USA</u> , 93:14564-14568.
C312	Gammon <i>et al.</i> , (1992), "Endogenous Loading of HLA-A2 Molecules with an Analog of the Influenza Virus Matrix Protein-Derived Peptide and Its Inhibition By An Exogenous Peptide Antagonist," <u>J. Immunol.</u> , 148:7-12.
C313	Ghetie <i>et al.</i> , (1990), "Disseminated or Localized Growth of a Human B-Cell Tumor (Daudi) in SCID Mice," <u>Intl. J. Cancer</u> , 45:485.
C314	Ghetie <i>et al.</i> , (1997), "FcRn: The MHC Class I-Related Receptor that is More Than an IgG Transporter," <u>Immunology Today</u> , 18(12):592-598.
C315	Goldwasser <i>et al.</i> , (1971), "Purification of Erythropoietin," <u>Proc. Natl. Acad. Sci. USA</u> , 68:697-8.
C316	Goldwasser <i>et al.</i> , (1975), "Erythropoietin: Assay and Study of its Mode of Action," <u>Methods Enzymol.</u> , 37(PtB):109-21.
C317	Gurewich <i>et al.</i> , (1988), "Characterization of the Intrinsic Fibrinolytic Properties of Pro-Urokinase Through a Study of Plasmin-Resistant Mutant Forms Produced by Site-Specific Mutagenesis of Lysine," <u>J. Clin. Invest.</u> , 82:1956-1962.
C318	Hashimoto <i>et al.</i> , (1999), "Differential Antitumor Effects of Administration of Recombinant IL-18 or Recombinant IL-12 are Mediated Primarily by Fas-Fas Ligand- and Perforin-Induced Tumor Apoptosis, Respectively," <u>J. Immunol.</u> , 163:583-9.
C319	Henikoff <i>et al.</i> , (1992), "Amino Acid Substitution Matrices from Protein Blocks," <u>Proc. Natl. Acad. Sci. USA</u> , 89:10915-10919.
C320	Hilgers <i>et al.</i> , (1999), "Sulfolipo-Cyclodextrin in Squalane-In-Water as a Novel and Safe Vaccine Adjuvant," <u>Vaccine</u> , 17:219-28.
C321	Hori <i>et al.</i> , (1987), "Establishment of an Interleukin 2-Dependent Human T Cell Line from a Patient with T Cell Chronic Lymphocytic Leukemia Who is Not Infected with Human T Cell Leukemia/Lymphoma Virus," <u>Blood</u> , 70:1069-72.
C322	Hulett <i>et al.</i> (1994), "Molecular Basis of Fc Receptor Function," <u>Adv. Immunol.</u> , 57:1127.
C323	Huston <i>et al.</i> , (1988), "Protein Engineering of Antibody Binding Sites: Recovery of Specific Activity in an Anti-Digoxin Single-Chain Fv Analogue Produced In <i>Escherichia Coli</i> ," <u>Proc. Natl. Acad. Sci. USA</u> , 85:5879-5883.
C324	Isaacs <i>et al.</i> , (1998), "Therapy with Monoclonal Antibodies. II. The Contribution of Fcγ Receptor Binding and the Influence of CH1 and CH3 Domains on In Vivo Effector Function," <u>J. Immunol.</u> , 161:3862-3869.
C325	Jacobs <i>et al.</i> , (1985), "Isolation and Characterization of Genomic And cDNA Clones of Human Erythropoietin," <u>Nature</u> , 313:806-10.

EXAMINER	DATE CONSIDERED
----------	-----------------

FORM PTO - 1449  SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO.: LEX-003  APPLICANT(S): Gillies <i>et al.</i>  SERIAL NO.: 09/256,156  FILING DATE: February 24, 1999 GROUP: 1647
--	---

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
C326	Jefferis <i>et al.</i> , (1990), "Molecular Definition of Interaction Sites on Human IgG for Fc Receptors huFcγR," <u>Mol. Immunol.</u> , 27(12):1237-1240.
C327	Karlin <i>et al.</i> , (1990), "Methods for Assessing the Statistical Significance of Molecular Sequence Features by Using General Scoring Schemes," <u>Proc. Natl. Acad. Sci. USA</u> , 87:2264-8.
C328	Karlin <i>et al.</i> , (1993), "Applications and Statistics for Multiple High-Scoring Segments in Molecular Sequences," <u>Proc. Natl. Acad. Sci. USA</u> , 90:5873-7.
C329	Karpusas <i>et al.</i> , (1997), "The Crystal Structure of Human Interferon β at 2.2-A Resolution," <u>Proc. Natl. Acad. Sci. USA</u> , 94:11813-11818.
C330	Kelner <i>et al.</i> , (1994), "Lymphotactin: A Cytokine that Represents a New Class of Chemokine," <u>Science</u> , 266:1395-9.
C331	King <i>et al.</i> , (2004), "Phase I Clinical Trial of the Immunocytokine EMD 273063 in Melanoma Patients," <u>J. Clin. Oncol.</u> , 22(22):4463-73.
C332	Klinman <i>et al.</i> , (1997), "Contribution of CpG Motifs to the Immunogenicity of DNA Vaccines," <u>J. Immunol.</u> , 158:3635-9.
C333	Ko <i>et al.</i> , (2004), "Safety, Pharmacokinetics, and Biological Pharmacodynamics of the Immunocytokine EMD 273066 (huKS-IL2)," <u>J. Immunotherapy</u> , 27:232-239.
C334	Kuntz <i>et al.</i> , (1982), "A Geometric Approach to Macromolecule-Ligand Interactions," <u>J. Mol. Biol.</u> , 161:269-88.
C335	Kurtz, (1982), "A New Candidate for the Regulation of Erythropoiesis. Insulin-Like Growth Factor I," <u>FEBLAL</u> , 149(1):105-8.
C336	Lai <i>et al.</i> , (1986), "Structural Characterization of Human Erythropoietin," <u>J. Biol. Chem.</u> , 261:3116-21.
C337	Lai <i>et al.</i> , (1998), "DNA Vaccines," <u>Crit. Rev. Immunol.</u> , 18:449-84.
C338	Lanza <i>et al.</i> , (1993), "Active Immunity against the CD4 Receptor by Using an Antibody Antigenized with Residues 41-55 of the First Extracellular Domain," <u>Proc. Natl. Acad. Sci. USA</u> , 90:11683-7.
C339	Lawn <i>et al.</i> , (1981), "DNA Sequence of a Major Human Leukocyte Interferon Gene," <u>Proc. Natl. Acad. Sci. USA</u> , 78:5435-9.
C340	Lin <i>et al.</i> , (1985), "Cloning and Expression of the Human Erythropoietin Gene," <u>Proc. Natl. Acad. Sci. USA</u> , 82:7580-4.
C341	Lin <i>et al.</i> , (1986), "Monkey Erythropoietin Gene: Cloning, Expression and Comparison with the Human Erythropoietin Gene," <u>Gene</u> , 44:201-9.
C342	Lode <i>et al.</i> , (1998), "Gene Therapy with a Single Chain Interleukin 12 Fusion Protein Induces T Cell-Dependent Protective Immunity in a Syngeneic Model of Murine Neuroblastoma," <u>Proc. Natl. Acad. Sci. USA</u> , 95:2475-80.

EXAMINER	DATE CONSIDERED
----------	-----------------

FORM PTO - 1449  SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO.: LEX-003  APPLICANT(S): Gillies <i>et al.</i>  SERIAL NO.: 09/256,156  FILING DATE: February 24, 1999 GROUP: 1647
--	---

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
C343	Lorenz <i>et al.</i> , (1999), "Induction of Anti-Tumor Immunity Elicited by Tumor Cells Expressing a Murine LFA-3 Analog Via a Recombinant Vaccinia Virus," <u>Hum. Gene Ther.</u> , 10:623-31.
C344	Lotze <i>et al.</i> , (1996), "Cytokine Gene Therapy of Cancer Using Interleukin-12: Murine and Clinical Trials," <u>Ann. NY Acad. Sci.</u> , 795:440-54.
C345	Macdougall <i>et al.</i> , (1999), "Pharmacokinetics of Novel Erythropoiesis Stimulating Protein Compared with Epoetin Alfa in Dialysis Patients," <u>J. Am. Soc. Nephrol.</u> , 10:2392-5.
C346	MacLean <i>et al.</i> , (1996), "Enhancing the Effect of Theratope STn-KLH Cancer Vaccine in Patients with Metastatic Breast Cancer by Pretreatment with Low-Dose Intravenous Cyclophosphamide," <u>J. Immunother.</u> , 19(4):309-316.
C347	Maghazachi <i>et al.</i> , (1997), "Interferon-Inducible Protein-10 and Lymphotactin Induce the Chemotaxis and Mobilization of Intracellular Calcium in Natural Killer Cells through Pertussis Toxin-Sensitive and -Insensitive Heterotrimeric G-Proteins," <u>FASEB J.</u> , 11:765-74.
C348	Mariani <i>et al.</i> , (1997), "Tumor Targeting Potential of the Monoclonal Antibody BC-1 against Oncofetal Fibronectin in Nude Mice Bearing Human Tumor Implants," <u>Cancer</u> , 80:2378-84.
C349	Marshall <i>et al.</i> , (1994), "Role of the Polymorphic Residues in HLA-DR Molecules in Allele-Specific Binding of Peptide Ligands," <u>J. Immunol.</u> , 152:4946-57.
C350	Marshall <i>et al.</i> , (1995), "Prediction of Peptide Affinity to HLA-DR Molecules," <u>Biomed. Pept. Proteins Nucleic Acids</u> , 1(3):157-62.
C351	McDonald, (1986), "Cloning, Sequencing, and Evolutionary Analysis of the Mouse Erythropoietin Gene," <u>Mol. Cell. Biol.</u> , 6:842-8.
C352	McGonigle <i>et al.</i> , (1984), "Erythropoietin Deficiency and Inhibition of Erythropoiesis in Renal Insufficiency," <u>Kidney Int.</u> , 25(2):437-44.
C353	McMahan <i>et al.</i> , (1991), "A Novel IL-1 Receptor, Cloned From B-Cells by Mammalian Expression is Expressed in Many Cell Types," <u>EMBO J.</u> , 10:2821-32.
C354	McMahon <i>et al.</i> , (1990), "Pharmacokinetics and Effects of Recombinant Human Erythropoietin after Intravenous and Subcutaneous Injections in Healthy Volunteers," <u>Blood</u> , 76:1718-22
C355	Mehrotra <i>et al.</i> , (1993), "Effects of IL-12 on the Generation of Cytotoxic Activity in Human CD8+ T Lymphocytes," <u>J. Immunol.</u> , 151:2444-52.
C356	Menard <i>et al.</i> , (1983), "Generation of Monoclonal Antibodies Reacting with Normal and Cancer Cells of Human Breast," <u>Cancer Res.</u> , 43:1295-300.
C357	Miyake <i>et al.</i> , (1977), "Purification of Human Erythropoietin," <u>J. Biol. Chem.</u> , 252:5558-64.
C358	Miyake <i>et al.</i> , (1988), "Synthesis of Recombinant Human Single-Chain Urokinase-Type Plasminogen Activator Variants Resistant to Plasmin and Thrombin," <u>J. Biochem.</u> , 104:643-647.

EXAMINER	DATE CONSIDERED
----------	-----------------

FORM PTO - 1449  SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO.: LEX-003  APPLICANT(S): Gillies <i>et al.</i>  SERIAL NO.: 09/256,156  FILING DATE: February 24, 1999 GROUP: 1647
--	---

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
C359	Morrison <i>et al.</i> , (1984), "Chimeric Human Antibody Molecules: Mouse Antigen-Binding Domains with Human Constant Region Domains," <u>Proc. Natl. Acad. Sci. USA</u> , 81:6851-5.
C360	Nagao <i>et al.</i> , (1992), "Nucleotide Sequence of Rat Erythropoietin," <u>Biochim. Biophys. Acta</u> , 1171(1):99-102.
C361	Nastala <i>et al.</i> , (1994), "Recombinant IL-12 Administration Induces Tumor Regression in Association with IFN- $\gamma$ Production," <u>J. Immunol.</u> , 153:1697-706.
C362	Naughton <i>et al.</i> , (1983), "Evidence for an Erythropoietin-Stimulating Factor in Patients with Renal and Hepatic Disease," <u>Acta Haemat.</u> , 69:171-9.
C363	Neal <i>et al.</i> , (2004), "Enhanced Activity of Hu14.18-IL2 Immunocytokine against Murine NXS2 Neuroblastoma when Combined with Interleukin-2 Therapy," <u>Clin. Cancer. Res.</u> , 10:4839-4847.
C364	Nelles <i>et al.</i> , (1987), "Characterization of Recombinant Human Single Chain Urokinase-Type Plaminogen Activator Mutants Produced by Site-Specific Mutagenesis of Lysine 158," <u>J. Biol. Chem.</u> , 262(12):5682-5689.
C365	Noguchi <i>et al.</i> , (1994), "A Mouse Mutant P53 Product Recognized by CD4+ and CD8+ T Cells," <u>Proc. Natl. Acad. Sci. USA</u> , 91:3171-5.
C366	Orlandi <i>et al.</i> , (1989), "Cloning Immunoglobulin Variable Domains for Expression by the Polymerase Chain Reaction," <u>Proc. Natl. Acad. Sci. USA</u> , 86:3833-7.
C367	Palucka <i>et al.</i> , (1998), "Dendritic Cells as the Terminal Stage of Monocyte Differentiation," <u>J. Immunol.</u> , 160:4587-95.
C368	Panina-Bordignon <i>et al.</i> , (1989), "Universally Immunogenic T Cell Epitopes: Promiscuous Binding to Human MHC Class II and Promiscuous <u>Recognition</u> by T Cells," <u>Eur. J. Immunol.</u> , 19:2237-42
C369	Pavlović-Kentera <i>et al.</i> , (1980), "Effects of Prostaglandin Synthetase Inhibitors, Salt Overload and Renomedullary Dissection on the Hypoxia Stimulated Erythropoietin Production in Rats," <u>Exp. Hematol.</u> , 8(Supp. 8):283-92.
C370	Pedley <i>et al.</i> (1999), "Enhancement of Antibody-Directed Enzyme Prodrug Therapy in Colorectal Xenografts by an Antivascular Agent," <u>Cancer Res.</u> , 59:3998-4003.
C371	Perussia <i>et al.</i> , (1992), "Natural Killer (NK) Cell Stimulatory Factor or IL-12 Has Differential Effects on the Proliferation of TCR- $\alpha\beta+$ , TCR- $\gamma\delta+$ T Lymphocytes, and NK Cells," <u>J. Immunol.</u> , 149:3495-502.
C372	Pluschke <i>et al.</i> , (1996), "Molecular Cloning of a Human Melanoma-Associated Chondroitin Sulfate Proteoglycan," <u>Proc. Natl. Acad. Sci. USA</u> , 93:9710-5.
C373	Poon <i>et al.</i> , (1995), "Structure and Function of Several Anti-Dansyl Chimeric Antibodies Formed by Domain Interchanges Between Human IgM and Mouse IgG2b," <u>J. Biol. Chem.</u> , 270:8571-7.
C374	Queen <i>et al.</i> , (1989), "A Humanized Antibody that Binds to the Interleukin 2 Receptor," <u>Proc. Natl. Acad. Sci. USA</u> , 86:10029-33.
C375	Radhakrishnan <i>et al.</i> , (1996), "Zinc Mediated Dimer of Human Interferon- $\alpha_{2b}$ Revealed by X-Ray Crystallography," <u>Structure</u> 4(12):1453-63.

EXAMINER	DATE CONSIDERED
----------	-----------------

FORM PTO - 1449  SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO.: LEX-003  APPLICANT(S): Gillies <i>et al.</i>  SERIAL NO.: 09/256,156  FILING DATE: February 24, 1999 GROUP: 1647
--	---

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
C376	Ramachandran <i>et al.</i> , (1968) "Conformation of Polypeptides and Proteins," <u>Adv. Prot. Chem.</u> , 23:283-299.
C377	Rarey <i>et al.</i> , (1995), "Time-Efficient Docking of Flexible Ligands into Active Sites Of Proteins," <u>Proc. Int. Conf. Intell. Syst. Mol. Biol.</u> , 3:300-8.
C378	Resegotti <i>et al.</i> , (1981), "Treatment of Aplastic Anaemia with Methenolone, Stanozolol and Nandrolone. A Report of 130 Cases," <u>Pan. Med.</u> , 23:243-8.
C379	Riechmann <i>et al.</i> , (1988), "Reshaping Human Antibodies for Therapy," <u>Nature</u> , 332:323-7.
C380	Robinson <i>et al.</i> , (1998), "Optimizing the Stability of Single-Chain Proteins by Linker Length and Composition Mutagenesis," <u>Proc. Natl. Acad. Sci. USA</u> , 95:5929-34.
C381	Rothmann <i>et al.</i> , (1982), "Erythropoietin-Dependent Erythrocytosis associated with Hepatic Angiosarcoma," <u>J. Surg. Oncol.</u> , 20:105-8.
C382	Runkel <i>et al.</i> , (1998), "Structural and Functional Differences Between Glycosylated and Non-Glycosylated Forms of Human Interferon- $\beta$ (IFN- $\beta$ )," <u>Pharmaceutical Res.</u> , 15:641-649.
C383	Sakano <i>et al.</i> , (1980), "Two Types of Somatic Recombination are Necessary for the Generation of Complete Immunoglobin Heavy-Chain Genes," <u>Nature</u> , 286:676-683.
C384	Sáli <i>et al.</i> , (1993), "Comparative Protein Modelling by Satisfaction of Spatial Restraints," <u>J. Mol. Biol.</u> , 234:779-815.
C385	Schecter <i>et al.</i> , (1997), "Tissue Factor is Induced by Monocyte Chemoattractant Protein-1 in Human Aortic Smooth Muscle And THP-1 Cells," <u>J. Biol. Chem.</u> , 272:28568-73.
C386	Sharp <i>et al.</i> , (1988), "Codon Usage Patterns in <i>Escherichia coli</i> , <i>Bacillus subtilis</i> , <i>Saccharomyces cerevisiae</i> , <i>Schizosaccharomyces pombe</i> , <i>Drosophila melanogaster</i> and <i>Homo sapiens</i> ; a Review of the Considerable Within-Species Diversity," <u>Nucleic Acids Res.</u> , 16(17):8207-8211.
C387	Simonsen <i>et al.</i> , (1983), "Isolation and Expression of an Altered Mouse Dihydrofolate Reductase cDNA," <u>Proc. Natl. Acad. Sci. USA</u> , 80:2495-2499.
C388	Smith <i>et al.</i> , (1981), "Identification of Common Molecular Subsequences," <u>J. Mol. Biol.</u> , 147:195-197.
C389	Soligo <i>et al.</i> , (1998), "Expansion of Dendritic Cells Derived from Human CD34+ Cells in Static And Continuous Perfusion Cultures," <u>Br. J. Haematol.</u> , 101:352-63.
C390	Spivak <i>et al.</i> , (1989), "The In Vivo Metabolism of Recombinant Human Erythropoietin in The Rat," <u>Blood</u> , 73:90-9.
C391	Sturniolo <i>et al.</i> , (1999), "Generation of Tissue-Specific and Promiscuous HLA Ligand Databases Using DNA Microarrays and Virtual HLA Class II Matrices," <u>Nat. Biotech.</u> , 17(6):555-61.
C392	Suliman <i>et al.</i> , (1996), "Cloning of a cDNA Encoding Bovine Erythropoietin and Analysis of Its Transcription in Selected Tissues," <u>Gene</u> , 171:275-80.

EXAMINER	DATE CONSIDERED
----------	-----------------

FORM PTO - 1449  SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO.: LEX-003  APPLICANT(S): Gillies <i>et al.</i>  SERIAL NO.: 09/256,156  FILING DATE: February 24, 1999 GROUP: 1647
--	---

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
C393	Taniguchi <i>et al.</i> , (1980), "Expression of the Human Fibroblast Interferon Gene in Escherichia Coli," <u>Proc. Natl. Acad. Sci. USA</u> , 77:5230-5233.
C394	Thurner, (1999), "Generation of Large Numbers of Fully Mature and Stable Dendritic Cells from Leukapheresis Products for Clinical Application," <u>J. Immunol. Methods</u> , 223:1-15.
C395	Tiruppathi <i>et al.</i> , (1996), "Isolation and Characterization of a Cell Surface Albumin-Binding Protein from Vascular Endothelial Cells," <u>Proc. Nat. Acad. Sci. USA</u> , 93:250-4.
C396	Van Den Eynde <i>et al.</i> , (1989), "Presence on a Human Melanoma of Multiple Antigens Recognized By Autologous CTL," <u>Int. J. Cancer</u> , 44:634-40.
C397	Van Der Bruggen <i>et al.</i> , (1991), "A Gene Encoding an Antigen Recognized by Cytolytic T Lymphocytes on a Human Melanoma," <u>Science</u> , 254:1643-7
C398	Van Heyningen <i>et al.</i> , (1982), "Human MHC Class II Molecules as Differentiation Markers," <u>Immunogenetics</u> , 16:459-69
C399	Voest <i>et al.</i> , (1995), "Inhibition of Angiogenesis in Vivo by Interleukin 12," <u>J. Natl. Canc. Inst.</u> , 87:581-6.
C400	Von Heijne <i>et al.</i> , (1986), "A New Method for Predicting Signal Sequence Cleavage Sites," <u>Nucleic Acid Res.</u> , 14:4683-4690.
C401	Ward <i>et al.</i> , (1995), "The Effector Functions of Immunoglobulins: Implications for Therapy," <u>Therapeutic. Immunology</u> , 2:77-94.
C402	Watson <i>et al.</i> , (1984), "Compilation of Published Signal Sequences," <u>Nucleic Acid Res.</u> , 12:5145-5164.
C403	Weber <i>et al.</i> , (2001), "Phase I Trial of huKS-IL2 Immunocytokine in Patients with Prostate Carcinoma: Clinical, PK, and Biological PD Results (Abstract)," <u>American Society of Clinical Oncology Program/Proceedings</u> , 20(Part 1):259a.
C404	Weitkamp <i>et al.</i> , (1973), "Additional Data on the Population Distribution of Human Serum Albumin Genes; Three New Variants," <u>Ann. Hum. Genet.</u> , 37:219-26.
C405	Woof <i>et al.</i> , (1986), "Localisation of the Monocyte-Binding Region on Human Immunoglobulin G," <u>Mol. Immunol.</u> , 23:319-30.
C406	Wyatt <i>et al.</i> , (1998), "The Antigenic Structure of the HIV gp120 Envelope Glycoprotein," <u>Nature</u> , 393:705-11.
C407	Wysocka <i>et al.</i> , (1995), "Interleukin-12 is Required for Interferon- $\gamma$ Production and Lethality in Lipopolysaccharide-Induced Shock in Mice," <u>Eur. J. Immunol.</u> , 25:672-6.
C408	Yan <i>et al.</i> , (1996), "Characterization of an Ig VH Idiotope that Results in Specific Homophilic Binding and Increased Avidity for Antigen," <u>J. Immunol.</u> , 157:1582-8.
C409	Yeh <i>et al.</i> , (1992), "Design of Yeast-Secreted Albumin Derivatives for Human Therapy: Biological and Antiviral Properties of a Serum Albumin-CD4 Genetic Conjugate," <u>Proc. Natl. Acad. Sci. USA</u> , 89:1904-8.

EXAMINER	DATE CONSIDERED
----------	-----------------

<b>FORM PTO - 1449</b> <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>	ATTORNEY DOCKET NO.: LEX-003 APPLICANT(S): Gillies <i>et al.</i> SERIAL NO.: 09/256,156 FILING DATE: February 24, 1999 GROUP: 1647
--	---

**OTHER ART, JOURNAL ARTICLES, ETC.**

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C410	Zhang <i>et al.</i> , (1994), "Structure/Activity Analysis of Human Monocyte Chemoattractant Protein-1 (MCP-1) by Mutagenesis," <u>J. Biol. Chem.</u> , 269:15918-24.
	C411	Zuckier <i>et al.</i> , (1998), "Chimeric Human-Mouse IgG Antibodies with Shuffled Constant Region Exons Demonstrate that Multiple Domains Contribute to In Vivo Half-Life," <u>Cancer Res.</u> , 58(17):3905-8.
EXAMINER		DATE CONSIDERED

BOS-818730 v1

EXAMINER	DATE CONSIDERED
----------	-----------------